Title: Multi-Level Instrument Organizer

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BACKGROUND OF THE INVENTION

The present invention relates to organizers and counters for surgical instruments retractable or expandable at an operative end by opposing action of the thumb and/or fingers in loops therefor at another end, cleaning and sterilization supports for such surgical instruments and thumb / finger loop hold down mechanisms for maintaining a single such loop of such surgical instruments secured to an organizer or counter therefor.

In US Patent 4,342,391, a device is described for storing sterile instruments and memorizing the count thereof. A main frame includes a plurality of juxtaposed boots, individually and selectively rotatable from open to closed positions. Each open boot stores the handle of an instrument and a rotatable cover plate is locked into position overlaying open and closed boots to apply holding contact pressure against instrument handles inserted in open boots. The number of open boots indicates the number of instruments selected to be stored by the device.

The present invention for a surgical instrument counter relates to the handling of tools and particularly surgical instruments, which must be sterilized, counted and carried securely without contact with each other, into an operating room. More specifically, the invention relates to a carrying, cleaning, security and sterilization device for surgical instruments, which retains the instruments in selected positions and indicates the total number of surgical instruments carried into an operating room, even though some or all of such instruments are removed from the device during a surgical procedure. Instruments selected for use in a surgical procedure are usually placed in a sterilization tray in which they are immovably positioned in a manner such that the opposing grasping or position extensions of such instruments do not come into contact with each other, thereby to reduce the surface area of small crevices produced by a certain range of operation of the device which makes full sterilization more difficult.

Locked instruments may not be sterilized due to lack of steam penetration during the sterilization cycle.

The tray and instruments are next sterilized together and then presented to operating room personnel for their intended use. It is extremely important that an accurate count be made of the number of instruments so sterilized and presented, and that a count of the number of dirty instruments removed after the surgical procedure is completed be equal to the first count. Otherwise, there is a great risk that one or more instruments unknowingly may have been left inside of a patient after the surgical procedure has been completed, and the surgical incision closed. Although a member of the operating room personnel is usually designated to keep track of the counts, the mental alertness and memory of such person must be relied upon not to make a mistake in counts.

In US Patent 4,229,420, a surgical instrument rack is described for holding, carrying, organizing, and counting a plurality of ring handled surgical instruments. The rack is formed of autoclavable polymeric material and includes two movable or separable members which coact with each other and with the surgical instruments to secure such instruments against release in parallel side-by-side relation with the handles and jaws (or blades) of such instruments separated slightly to facilitate sterilization of their surfaces. The structural relationship of parts responsible for the retention and automatic camming of the instruments into such slightly open positions is disclosed. Surgical procedures are regularly performed using "sets" of preselected surgical instruments, each set being a collection of instruments established from experience to be useful for a given surgical procedure. For example, the surgical instruments expected to be used in an obstetrical procedure are grouped together to form a set and, as a set, are sterilized, stored on a tray or pan, and finally transported upon that tray to the operating arena when their use is required.

Ring-handled instruments (clamps, forceps, scissors, needle holders, etc.) have often been grouped together in such sets by the use of clips which are extended through the corresponding handle loops of the instruments which comprise the sets, usually with the handles of such instruments spread apart to facilitate cleaning and sterilization. Instead of clips, some hospitals use instrument racks having upstanding

pegs for holding a stack of ring-handled instruments with the pegs of the rack projecting upwardly through the handle loops. In still other instances, sets of ring-handled surgical instruments have been grouped together by fashioning a makeshift clip from a pair of instruments in such a way that each set is locked together. Clips, holders, and racks typifying the structures used in the past for supporting ring-handled surgical instruments are disclosed in catalogs for such instruments.

It is well known that such surgical instrument sets often must include, in a side by side relationship, two general classes of instruments, for purposes of handling, cleaning and organizing, representing extremes in instrument lengths. A general longest length group includes those instruments with long sets of opposing jaws, towel clamps, and the like, the group generally comprising instruments with a length from tip to ring handle of about 9-18 inches. The general shortest length group includes small hemostats, dissection scissors and the like, the group generally comprising instruments with a length from tip to ring handle of about 4-5 inches. The requirement to include these instruments in a side by side relationship whereafter they must be quickly and with high efficiency cleaned, sterilized, used in a surgical procedure and returned for another such sequence poses clear difficulties for the cleaning, counting and handling staff.

In US Patent 3,925,014, a rack is described for storing and supporting, at the time of use, sterile hinged instruments. The rack is comprised of an openwork frame and includes a pair of removable retaining bars which respectively hold the instruments in the open position during sterilization and retain the instruments on the rack until use thereof is desired regardless of the position of the rack.

As described above, In the routine handling of surgical instruments care must be taken to insure that all instruments have been thoroughly cleaned prior to sterilization. Thus, the instruments will first be subjected to a cleaning which may include immersion in an ultra-sonic bath to remove all foreign matter. Thereafter, the instruments will be assembled into a basic set, and the set will be arranged in a perforated or wire-meshed bottom tray for sterilization. During cleaning and sterilization all jointed instruments must be open or unlocked to permit contact of the steam with all surfaces.

In the operating room the instruments will typically be removed from the tray in which they have been sterilized and will be arranged between a sterile back table and Mayo stand, the Mayo stand typically located over the patient, in a manner which permits their being handed to the surgeon as needed without delay. The arrangement of a plurality of instruments, for example jointed clamps, in loose fashion on the stand presents the possibility of accidental droppage thus often necessitating emergency sterilization. The numerous manipulative steps required between each use also presents the possibility that an instrument may be inadvertently misplaced and thus will not be in a basic set when needed.

For the reasons briefly discussed above, there is a need and desire for a technique and apparatus which will minimize the handling of instruments during the cleansing process by eliminating the preparation for each basic step in the cleaning technique. For jointed instruments this requires that some means be provided for facilitating the opening and retaining of the instruments in the open condition during cleaning and sterilization. A concomitant desire is the elimination of the possibility of loss of any instrument from a basic set during processing. This desire may be expressed in terms of the objective of keeping the instruments of a basic set together at all times except when the instruments are in the surgeon's hands.

In US Patent 5145655, a support rack for ring handled instruments is described with an expandable two-section base. The device suffer from an unavoidable lack of lateral supports for instruments other than two supports, one at the end of each base section. Thus, for groups of instruments over a count of about five, removal of a few instruments results in the instruments falling substantially as flat on the surface of the device as if there had been no device at all.

SUMMARY OF THE INVENTION

The present invention comprises an instrument counter with a plurality of counting zones each comprising a lower ring handle well for a single instrument, lower shaft support surface and opposing separation fins extending upward from the lower shaft support surface, thereby providing counting separation and support such that the tips of

all the ring handled instruments, from longest to shortest, rest on the same flat surface as the instrument counter and each instrument is held in a substantially horizontally vertical position.

The present invention also comprises an instrument organizer comprising an end well extending to a lower shaft support surface for a lower ring handle loop for single instrument which thereby becomes the end support for an instrument rack. The instrument organizer further comprises a multi-instrument lower ring handle well immediately adjacent to the single instrument well, the multi-instrument well also extending to a multi-instrument lower shaft support surface, such support surface further comprising a support fin parallel to supported instruments located on the multi-instrument lower shaft support surface from 2-5 instrument thicknesses from the single instrument support surface.

The present invention also comprises a top ring handle support having a certain range of support. The range is defined by a particular configuration of a ring handle instrument for cleaning, carrying and sterilization. Any ring handle instrument rack may benefit from providing support within this range, such that the instrument rack provides that the tip of a horizontally vertical (i.e., on its long edges) instrument rests on a surface with the lowest surface of its lower ring handle being about less than one inch above that surface. The present invention includes a range of support for side by side ring handled instruments such that the instruments from the longest and shortest group may be held open sufficiently for current practice in cleaning, carrying and sterilization using the same elevation. There exists a range bounded by the arc travel of the inside open loops of the ring handles of the side by side instruments which will accommodate a single straight support wire or bar such that the shortest group instruments are not opened beyond the widest point at which they still contact the tip support surface while the longest group instruments are not so allowed to close enough to permit the opposing jaws of the instrument to close or to latch closed.

The present invention also comprises a ring handle instrument restraint wire or bar with a short travel arc for securing the lower ring handle of those instruments to an instrument rack. Preferably, a pivot attachment is made to each side of an instrument

rack of a relatively short arm connected to the restraint wire. The novel short travel arc is just sufficient to restrain longest group instruments' lower ring handle loops (at or less than about 29mm x 35mm) in a side by side relationship with the lower ring handle loops of the shortest group instruments. It has been found that providing an instrument rack with this restraint wire permits single hand carrying of a full rack of large and small group instruments with no loss or dropping of instruments. The restraint is mostly self actuating, i.e., as the rack to which the instruments are secured by this restraint wire is lifted, the heavier shaft end levers downward and the fulcrum of the lower shaft support surface of the instrument rack causes the furthest end of the lower ring handle to lever upwards. The location of the wire restraint across the inner edge of the lower ring handle is sufficiently close to the fulcrum surface so that the levering action forces the wire restraint into a more secure position for the ring handles than when the assembled items were on a horizontal surface.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a top view of an instrument counter according to the present invention.

Figure 2 is a side view of a cleaning and sterilization support (hereafter top ring handle support) used with both the instrument counter and organizer.

Figure 3 is a bottom view of the instrument counter.

Figure 4 is a front view of the instrument counter.

Figure 5 is an end view of the instrument counter.

Figure 6 is a cross section BB of Figure 1.

Figure 7 is a cross section AA of Figure 1.

Figure 8 is a pivotable wire restraint easily clipped to the instrument counter.

Figure 9 is an end view of the pivotable wire restraint of Figure 8.

Figure 10 is cross section BB of Figure 1 with an end view of the pivotable wire restraint shown in open and restraining positions.

Figure 11 is cross section AA of Figure 1 with a cross section 305 of Figure 8 of the pivotable wire restraint shown in open and restraining positions for the class of instruments in the longest group.

Figure 12 is cross section AA of Figure 1 with a cross section 305 of Figure 8 of the pivotable wire restraint shown in open and restraining positions for the class of instruments in the shortest group.

Figure 13 is the top ring handle support of Figure 2 shown secured to an instrument counter in the view of Figure 4.

Figure 14 is the top ring handle support of Figure 2 shown secured to an instrument counter in the view of Figure 1.

Figure 15 is cross section AA of Figure 1 with a cross section 205 of Figure 13 of the top ring handle support shown in a support position for the class of instruments in the longest group.

Figure 16 is cross section AA of Figure 1 with a cross section 205 of Figure 13 of the top ring handle support shown in a support position for the class of instruments in the shortest group.

Figure 17 is a broken away section of the instrument counter of Figure 1, with a narrowed travel and support slot for the pivotable wire restraint.

Figure 18 is a top view of an instrument counter with a narrowed travel and support slot for the pivotable wire restraint and a undivided lower loop handle resting surface.

Figure 19 is a top view of an instrument organizer.

Figure 20 is a second top view of the instrument organizer of Figure 19.

Figure 21 is a front view of the instrument organizer of Figure 19.

Figure 22 is a cross section EE of the instrument organizer of Figure 19.

Figure 23 is a cross section HH of the instrument organizer of Figure 19.

Figure 24 is a cross section II of the instrument organizer of Figure 19.

Figure 25 is an end view of the instrument organizer of Figure 19.

Figure 26 is a pivotable wire restraint easily clipped to both the instrument organizer.

Figure 27 is an end view of the pivotable wire restraint of Figure 26.

Figure 28 is cross section EE of Figure 19 with an end view of the pivotable wire restraint shown in open and restraining positions.

Figure 29 is cross section II of Figure 19 with a cross section 705 of Figure 26 of the pivotable wire restraint shown in open and restraining positions for the class of instruments in the longest group.

Figure 30 is cross section II of Figure 19 with a cross section 705 of Figure 26 of the pivotable wire restraint shown in open and restraining positions for the class of instruments in the shortest group.

Figure 31 is cross section II of Figure 19 with a cross section 205 of Figure 13 of the top ring handle support shown in a support position for the class of instruments in the longest group.

Figure 32 is cross section II of Figure 19 with a cross section 205 of Figure of the top ring handle support shown in a support position for the class of instruments in the shortest group.

Figure 33 is a pivotable wire restraint easily clipped to both the instrument organizer and includes a further extension to provide external, unsecured top ring handle support.

Figure 34 is an end view of the pivotable wire restraint of Figure 33.

Figure 35 is cross section EE of Figure 19 with an end view of the pivotable wire restraint of Figure 33 shown in open and restraining positions.

Figure 36 is cross section II of Figure 19 with a cross section 805 of Figure 33 of the pivotable wire restraint shown in open and restraining positions for the class of instruments in the longest group.

Figures 37 to 46 are views of a multi-level embodiment of the invention.

Figure 37 is a rearward perspective view of a first section (shown lowermost) that slides into and beneath a second section (shown uppermost in a front perspective view) with a direction arrow indicating where the first section is intended to be inserted into the second section.

Figures 38 and 39 are front and top views respectively of the second section of Figure 37.

Figure 40 is a top view of the first section of Figure 37.

Figures 41 and 42 are respectively rear and top views of the first section secured partly into the second section.

Figure 43 is an end view of Figures 41 and 42.

Figure 44 is an end view of a second section showing the opening for inserting the first section.

Figure 45 is cross section 50 of Figures 41 and 42.

Figure 46 the first section of Figure 44 shown without the second section and with a ring handle surgical instrument resting in a substantially vertically planar orientation.

Figure 47 the second section of Figure 44 shown without the first section and with a ring handle surgical instrument resting in a substantially vertically planar orientation.

Figure 48 is a rear and perspective view of an alternate embodiment of the assembly of Figure 42.

Figure 49 is top perspective view of an alternate embodiment of the device of Figure 1 for low profile stacking.

Figures 50 and 51 are respectively front and rear perspective views of the device of Figure 49.

Figures 52 and 53 are respectively top end and bottom end perspective views of the device of Figure 49.

Figure 54 shows a front perspective view of two devices as shown in Figure 49 with a rearward edge engaged to initiate stacking.

Figure 55 shows a top perspective view of the two devices of Figure 54 in a compact stack.

Figure 56 shows an upper perspective close up of one end of the devices of Figure 55 and of part of connecting means on an end of the device of Figure 49..

Figure 57 shows an upper perspective close up of part of connecting means on an end of the device of Figure 49.

DETAILED DESCRIPTION OF THE INVENTION

The instrument counter of the present invention is shown in Figure 1. Identical aspect numbers in the figures represent substantially the same aspect. Counter 100 comprises a rectangular shape with raised separation fins 102 with inclined lower shaft support surfaces 103 therebetween. A portion of top surface 106 separates single

instrument lower ring handle wells 107 from the inclined support surfaces 103 wherein are preferably located counter section 101 numbers identifying single instruments placed in each counting section. Each of wells 107 have at their bottom a hole 106 to permit drainage of liquids during surgery, cleaning and sterilization. Preferably, a counting section also comprises a stepped down surface 105 on which is preferably imprinted numbers identifying single instruments placed in each counting section. End separation fins 109 may be somewhat thicker than those in between them for added overall structural support to the counter 100.

Top ring handle support bar holes 110 are formed through the top surface 106 and extend to an effective length with a somewhat oval cross section to resist axial twisting of the top ring handle support bar within holes 110. Holes 110 are formed at each end of a set of counting sections 101 through the top surface 106 in the lower shaft support surface between the inclined supports surfaces 103 and the leading edges of wells 107. This placement is critical to the function of the top ring handle support bars in one of the embodiments of this invention. As shown in Figure 2, top ring handle support bar 200 comprises an L-shaped round stainless steel rod about 1/8 inch in diameter. Centerline 115 is a broken line extending from the centerline of hole 110 to the centerline of the length 202 insertable in it. Length 202 defines the length of support bar 200 which is capable of bearing the inner edge of the top ring handle of an instrument. Section 204 shows the flattened portion of length 202 adapted to prevent turning about its axis when the bar 200 is inserted in hole 110.

Slot 111 is cut through surface 106 exposing a void thereunder between an outer sidewall of an end well 107 and the inner sidewall of counter 100, whereby the outer surface of this counter sidewall is shown in Figure 5. Between the outer sidewall of an end well 107 and the inner sidewall of counter 100 there spans a short, integrally molded shaft 112 sufficient to support pivotable attachment of the wire restraint described below. The slot 111 and shaft 112 cooperate with the wire restraint to define a support and travel path of the wire restraint to within bounds of acceptable operation for that aspect of the present invention.

Two attachment hooks 114 extending above surface 106 are formed about holes 113 to provide easy attachment of bar 200 along length 201. The bar is thus conveniently attachable for optional use of the bar 200 with counter 100.

The rectangular dimensions of surface 106 are about 120mm x 54mm. As shown in Figure 7, depth 125 of well 107 is about 17mm and width 124 is about 36mm. The side to side width of each well 107 is about 7-8mm. As it relates to the proper dimensions of the present invention, counter 100 is preferably molded as a single unit of re-sterilizable polymer (as an example, glass filled polypropylene) about 2mm thick. It is more preferred to form counter 100 of a material which will be stiffer and of greater life in re-usable (sterilizable) form, such materials including Amoco Polymers' (Alphanetta, GA) Radel® A or R resins. Counter 100 is formed with rounded corners to reduce risk of puncturing gloved hands of surgical personnel.

As shown in Figure 5, fins 102 extend above surface 106 by about a height 120 of at least about 10mm. As shown in the figures with instruments from the longest and shortest group, this height prevents side to side movement of the lower shaft of a ring handled instrument such that counting and individual separation of the instruments are accomplished within the capability of the typical staff person to perceive them. As shown in Figure 4, fins 102 have a tapered thickness of about from 2mm to 3mm. Width 118 between fins 102 is about 5mm and extends downward to the concave surface 103.

As in Figure 5, the portion of surface 106 between the leading edge of wells 107 and the downward slope of surface 103 is defined by width 123, which is preferably about 7mm. Horizontal width 122 of surface 103 is about 8mm and has a vertical height 121 of about 15mm.

The combination of these specific measurements of the aspects of each counting section 101 permits all of the instruments of the longest and shortest groups to rest the tip of the instrument solidly on a horizontal surface parallel with surface 106 supporting counter 100 while maintaining the lowest edge of the lower ring handle near or touching the bottom of well 107 and having the lower shaft connected to the lower ring handle directed substantially perpendicular to the front of counter 100 by contact with at least

one of the fins 102. It is possible to alter the present dimensions above to achieve the same objects just described, although the prior art has not before indicated that such a range of operation was possible. The aspect of resting the tip of the instrument on the surgical tray surface is critical to successful operation of a instrument tray. If supporting surface 106 at width 123 is too high, the smallest group instruments with present tips in the air that could catch on rubber gloves and up-end the instrument tray. If surface 106 is too low, wells 107 will not provide single instrument support sufficient to give easily countable separation. If fins 102 are too short, the lower shaft of each instrument of the longest group could move from side to side and interfere with the adjacent instrument. It is presented that the objects of the instrument counter are obtained with a plurality of adjacent counting sections 101.

The bottom of counter 100 is shown in Figure 3 with outer surface 107' of well 107 and further showing the shaft 112 connecting the outer surface 107' of an end well with the inner side wall of counter 100. Figure 4 is view CC of Figure 3. Figure 5 is view DD of Figure 3. The formed portion 110' is a molded section structurally enclosing hole 110.

Figure 6 shows a cross section of a fin 102, showing the solid molded construction. Figures 5-7 show a slight distance between the lowest part of surface 107' and a horizontal surface on which counter 100 would be placed. With the disclosed dimensions, that small distance can be appreciated, but is preferred so that the bottom outside surface of well 107 does not interfere with the flush seating of the bottom edge of counter 100 with such a horizontal surface.

With respect to the support bar 200, additional disclosure is made with reference to Figures 13-16. Zone 207 generally defines the three dimensional zone in which the ring handled instrument will be secured with that bar 200. The method of securely supporting a set of instruments in counter 100 is now described. As shown in Figure 12, bar 200 may be secured to the two hooks 114. The staff person removes the bar 200 and threads the free end of length 201 through the top ring handles of the several sized instruments. This threading process, in combination with the novel presentation of the counter of instruments in the longest and shortest groups, is relatively easily

done, i.e., a lateral up and down motion is used so to move the end of length 201 up and down thereby to bring the end of length 201 to the open side of the top ring handle. At the end of the lateral motion, all the top ring handles of the instruments seated with their lower ring handles in the counter wells 107 will be easily raised and the operator will then easily insert the length 202 into hole 110. At this insertion, as shown in Figures 15 and 16, the largest group instruments 400 and the smallest group instruments 500, respectively, will have their opposing operative jaws so sufficiently drawn apart to permit easy cleaning and sterilization. In Figure 13, height 206 is shown to be the height to which cross section 205 of length 201 is raised for effective top ring handle support. This height is at least about 76mm. The top of the effective range 208 in which both groups of instruments can be supported together for cleaning and sterilization is about 90mm, although the height of the standard cleaning basket is somewhat lower. The top of the range 208 at which a lower tip of the instrument will still contact the horizontal tray surface on which the counter rests is about 80-82mm from surface 106.

It has not been previously known to use a single, removable L-shaped support bar for raising top ring handles for instruments according to the present invention. Support bar 200 can be inserted from the right or left of a set of ring handled instruments for insertion into a right or left hole 110. If especially heavy instruments must be supported, two support bars 110 may be used in opposing insertion through the top ring handles of the instruments.

With respect to the embodiment of the present invention relating to a restraint wire, such a wire is shown in Figures 8 and 9. The inverted U-shape is effective for use in combination with the above counter 100 as the molded shaft 112 and slot 111 may be added with some additional cost to the counter. Restraint wire 300 comprises an effective arm height 302 for the two side arms, starting at a centerline 303 through the center of clip end 301 and extending upward to restraint section length 304, with a length for this embodiment of about 135mm.

Height 302 is critical to the effectiveness of the operation of restraint wire 300 -- in this embodiment height 302 is a minimum of about 25mm. When clipped to shaft 112

as in Figure 10, cross section 305 is shown in an open position 305A, whereby the arms of the U-shape rest against the back of slot 111. When the lower ring handles of the instruments are inserted into wells 107, restraint section length 304 is moved through path 306 so that cross section 305 reaches closed position 305B. Position 305B must be a minimum of about 11mm about surface 106 for the above counter. The minimum height can be reduced to about 9mm if the depth of the first well is increased to about 17mm or if a raised notch in the length 304 is made to accommodate a longest group instrument in the first well 107 at either end of the counter 100. Other longest group instruments in other wells further from the arms of the U-shaped restraint wire 300 will not restrain movement of the restraint length 304 over the lower ring handles, as is the case with those instruments in the first position. The restraint wire (preferably 1/16 stainless steel wire) will flex sufficiently to easily move over those longest group instrument ring handles, in other than the first positions, to position 305B. Figures 11 and 12 show the largest group instruments 400 and the smallest group instruments 500, respectively, having the restraint wire length in position 305B whereby downward levering of the longer forward portion of the instruments will clearly cause the lower ring handle to the right of a vertical line down from position 305B to lever upward, urging the wire restraint to the left, further increasing the securement of the restraint wire by increasing the tension on the wire against shaft 112.

Figure 17 shows an alternate embodiment for slot 111 as slot 131 with a narrowed forward section, whereby forward motion of the wire restraint forces a friction securement of the arm of the U-shaped wire restraint 300. Figure 18 shows an alternate embodiment of the counter 100 with no single wells for each ring handled instrument. The embodiment of Figure 18 would be minimally effective as a counter only for shortest group instruments whose upper and lower shafts are deflected by the fins 102.

An instrument organizer 600 is shown in Figure 19. The object of this invention is to provide a replacement for the towel placement under the lower edges of a set adjacent of ring handled instruments to prevent them from collapsing sideways from a substantially horizontally vertical position. Compared to the present invention

instrument organizer, prior art instrument organizing multiple instrument trays, with simple visual inspection, use a greater space to present all the needed instruments for a given procedure in the crowded space of a surgical tray or table. The segmentable and attachable pieces of the instrument organizers of the Figures comprise parts of a potentially very long instrument organizing panel, where each segment is attached easily and securely end to end, thereby easily and limitlessly expanding the instrument organizing capacity for all procedures.

The counting function of the above instrument counter is not intended, as single instrument slots are not provided for more than two of the instruments. The object of this instrument organizer is to minimize structure (as well as cost) while providing sufficient structure so that when any number of instruments are removed in a surgical procedure, any remaining instrument will present to the instrument remover an easily grasped top ring handle and/or pair of shafts. The easy grasping is achieved by maintaining a plane through the shaft axes at always above 45 degrees from the horizontal of the surgical tray on which the organizer rests. Since all handling of surgical instruments is done with gloved hands, maintaining this orientation is critical to effectiveness of any instrument holding device in surgery. The prior art shows many devices with much unnecessary structure or insufficient structure, as in US Patent 5145655, whereby when adjacent instruments are removed, the remaining instruments just fall on their side. Especially notable in US Patent 5145655 is the requirement for structure for an end wall above the surface supporting the lowest edge of the lower shaft of the instruments.

The present instrument organizer, on the other hand, has no end wall above top surface 603. Single instrument wells 610 with a depths, widths and lengths of about 17mm x 5mm x 36mm form, when the lower ring handle of any sized ring handled instrument is inserted and oriented to a forward position, the only needed end wall support for the other instruments whose ring handles are placed in the adjacent first multi-instrument wells 601. The inclined surface 609 is the forward surface of the organizer 600, whereupon rest or above which lie the lowest edges of the lower shafts of the ring handled instruments to be supported in the organizer 600 and which are

located major fins 606 and minor fins 608, with a lateral lower shaft support function somewhat analogous to fins 102 of the instrument counter 100, although the fins of the organizer are reduced to a minimum solely for grasping support.

A second multi-instrument well 602 comprises a width sufficient to hold a range of from 8 to 12 instruments side by side (about 42mm), where the wells 601 comprise a width sufficient to hold a range of from 6 to 9 instruments side by side (about 32mm). The depth and length of wells 601 and 602 are about that of the wells 610. Major well separators 604 are about in center of the widths of wells 601 and 602 and act to prevent sideways slippage of the lower ring handles of the supported instruments. Optionally, but preferably, single minor well separators 605 are located at some distance between major separators 604 and the side walls of wells 601 and 602. As shown in Figure 22, well separators 619 extend from the floors of the multi-instrument wells to the level of surface 103 to provide full support above the level of the major well separators 604.

As shown in Figures 21 and 22, the fins and separators have various heights, but have a thickness of about 1.5mm. The major fins 606 have a height of about 14mm above surface 603. The minor fins 608 have a height of about 2mm above surface 603. Inclined surface 609 is about 11mm long and drops about 3mm away from the horizontal surface 603. Major separators 604 have a height of about 5mm. Minor separators 605 have a height of about 2mm. Overall, the organizer is about 1.5mm thick.

Figure 21, view FF of Figure 19, shows the configuration of organizer section joining means 616. Such means are shown in Figure 25, view GG of Figure 19, to have upward lugs 620 adapted to slide upward in around shaft 612 and thus permit joining of several organizers together end to end. The overall length of the organizer is about 132mm and the width is about 60mm. With the inclusion of the end wells 611, the instrument organizer 600 can effectively support through a surgical procedure up to 32 instruments.

Figures 26-30 show inclusion of the restraint wire of the present invention as adapted to the instrument organizer.

Restraint wire 700 comprises an effective arm height 702 for the two side arms, starting at a centerline 703 through the center of clip end 701 and extending upward to restraint section length 704, with a length for this embodiment of about 128mm.

Height 702 is critical to the effectiveness of the operation of restraint wire 700 -- in this embodiment height 702 is a minimum of about 25mm. When clipped to shaft 612, cross section 705 is shown in an open position 705A, whereby the arms of the U-shape rest against the back of slot 611. When the lower ring handles of the instruments are inserted into wells of organizer 600, restraint section length 704 is moved through path 706 so that cross section 705 reaches closed position 705B. Position 705B must be a minimum of about 11mm about surface 603. The minimum height can be reduced to about 9mm if the depth of the first well is increased to about 17mm or if a raised notch in the length 704 is made to accommodate a longest group instrument in the first well 610. Other longest group instruments in other wells further from the arms of the U-shaped restraint wire 700 will not restrain movement of the restraint length 704 over the lower ring handles, as is the case with those instruments in the first position. The restraint wire (preferably 1/16 stainless steel wire) will flex sufficiently to easily move over those longest group instrument ring handles, in other than the first positions, to position 705B. Figures 29 and 30 show the largest group instruments 400 and the smallest group instruments 500, respectively, having the restraint wire length in position 705B whereby downward levering of the longer forward portion of the instruments will clearly cause the lower ring handle to the right of a vertical line down from position 705B to lever upward, urging the wire restraint to the left, further increasing the securement of the restraint wire by increasing the tension on the wire against shaft 612.

Figures 31 and 32 show the analogous operation of the top ring handle support bar 200 inserted as described above in holes 615.

Figures 34-36 show an alternate embodiment of the present invention with a combination device incorporating, although somewhat less effectively, the functions of the restraint wire and the top ring handle support bar.

Restraint wire and support bar 800 comprises an effective arm height 802 for the two side arms, starting at a centerline 803 through the center of clip end 801 and extending upward to restraint section length 804, with a length for this embodiment of about 135mm.

Height 802 is critical to the effectiveness of the operation of restraint wire 300 -- in this embodiment height 802 is a minimum of about 25mm. However, another U-shaped extension is added above the restraint wire at an angle out of the plane of the restraint wire, as shown in Figure 34. The added U-shaped section is intended to lift the lower outer edge of the top ring handles as the wire/bar 800 is moved from an open position at 305A/805A to into a forward closed position 305B/805B along path 306. Figure 36 shows a longest group instrument 400 would be effectively raised to a minimally open position for cleaning and sterilization with the wire/bar 800 device. This embodiment suffers from the lack of security to prevent the top shaft of the instruments from falling into a fully open arc if the instrument rack were mishandled. The top ring handle support bar 200 secures the inside edges of the top ring handles and thereby avoids that danger.

The location and function of slots 611/shafts 612, holes 613/hooks 614 and holes 615/section 615' are analogous to the location and functions, respectively of, for instrument counter 100, slots 111/shafts 112, holes 113/hooks 114 and holes 110/section 110'.

Figures 37 to 46 show a multi-level embodiment of the present invention. This embodiment stands surgical instruments edgewise and parallel to each other as in many of the above embodiments. This multi-level embodiment is formed in two sections, a first section and a second section. The first section slides into the hollowed out second section so that the two sections are fixed securely together.

In making the first section slide into and beneath the second section, a top row of shank ribs on the upper surfaces of the first section are adapted to easily retain and organize shorter, smaller surgical instruments. In contrast, a top row of shank ribs on the upper surfaces of the second section are elevated substantially higher than that top row on the first section to allow the nesting action of the first section into the second

section. The higher elevation of the top row of the second section means that it is better suited to retaining and organizing longer, larger surgical instruments. It is intended that when the phrase "surgical instruments" is used, it shall mean scissor action instruments with two shanks that rotate about a pivot with finger rings at two proximate ends of the shanks. The finger rings are adapted to allow a user to insert a thumb and forefinger into them to operate the scissor action instrument, such as hemostats or scissors. The scissor action of the surgical instruments causes them to operate in an operation plane defined by the scissor action.

When such instruments rotate about their pivot, they become easily entangled in other similar instruments. Most surgical procedures require such a large number of surgical instruments that they must be very carefully counted to reduce the risk of leaving an instrument in a patient. Thus, an effective surgical instrument organizer has multiple roles – retaining the surgical instruments in the most easily accessible and countable way while minimizing space on the operating room. Keeping the surgical instruments side by side and vertically edgewise is an excellent way to pick them up and count them. However, surgical instruments are made in a wide array of shaft lengths in order to perform tasks that are close to or far from the hand of the surgeon. In addition, stacking surgical instruments vertically edgewise against one another means that when one instrument is withdrawn, the remaining instruments collapse in a somewhat disorderly head while an attendant pushes them back together again.

The present multi-level embodiment solves the problem of finding a surgical instrument organizer that can stand surgical instruments independently and vertically edgewise in separated slots with minimal ribbing – and forming separate sections for large and small instruments. The nested first section is so substantially smaller in elevation than a second section that the ribbed surfaces of the first section are especially adapted to retain and organize smaller instruments.

In addition, the multi-level embodiment includes the use of small bumps or slot end ribs at an open end of a finger ring slot to keep the surgical instrument from sliding rearward. Some of the previous and above embodiments use boxed end slots to keep the lower finger rings fixed in the organizer. The multi-level embodiment can eliminate

the boxed end with the use of the small bumps or slot end ribs to keep the lower finger ring from sliding rearward, reducing size, cost and manufacturing complexity of the entire organizer.

In the most preferred form, the multi-level embodiment is formed entirely of two continuously molded pieces of plastic. The hollowed out shapes of the first and second sections are especially adapted to be formed in a molding operation from polymer resin, keeping the cost very low.

Figure 37 shows first section 1 in a front view. That orientation is to be changed by 180 degrees so that section 1 can be moved in direction 60 for insertion into an open end 33 of a second section 2. Section 2 is shown is a rearward view, the direction that a user would use to approach the assembled sections 1 and 2 to retain, organize and present for use a set of surgical instruments. Section 1 has a top ribbed shank row 22 and section 2 has a top ribbed shank row 7 where shanks near a finger ring of a surgical instrument will rest to be separated from other surgical instruments. Section 1 has a lower ribbed finger ring row 18 and section 2 has a lower ribbed finger ring row 12 where a lateral part of a finger ring of a surgical instrument will rest to be separated from other surgical instruments.

The combination of an aligned set of U-shaped slots in the upper rows and the lower rows of ribbed surfaces results in a operational slot for a segregating a surgical instrument in a vertically edgewise position. In section 1, U-shaped slots (1) in row 22 comprise shank ribs 25 and bottom surface 26 and (2) in row 18 comprise finger ring ribs 19 and bottom surface 20. In section 2, U-shaped slots (1) in row 7 comprise shank ribs 5 and bottom surface 4 and (2) in row 12 comprise finger ring ribs 13 and bottom surface 14. For section 1 and section 2, respectively, riser wall 38 (in Figure 38) and riser wall 32 form a box end for a forward part of the U-shaped slots, where those U-shaped slots are intended to be open at rearward parts (as in part 36 in Figure 40).

Section 1 comprises ends 35 and 36, of which end 36 is the leading end for insertion into an end 33 of section 2, which also comprises an opposite end 31. Section 1 and section 2 generally have longitudinal axes. When section 1 is inserted into section 2, those axes are substantially parallel. At end 36 of section 1, front wall 30, top surface

29, and the other integral parts have a cross section shape (radially from section 1's longitudinal axis) adapted to fit with relatively close tolerance into an opening in end 33 of section 2.

Continuing the insertion operation, when section 1 is fully inserted into section 2, (1) surface 29 and the tops of ribs 25 of top row 22 lie just beneath an underside of the top row 7 of section 2 and (2) the tops of lower row 18 of section 1 lie just beneath an underside of the lower row 12 of section 2. A cavity within section 2 is adapted to entirely contain section 1 except for sliding means for securing section 1 to section 2. Those sliding means in this particular embodiment comprise ledges 10 and 11 of section sliding respectively over an upper surface of ledges 17 and 27 of section 1, where ledge 10 is thereby captured by tabs 28 and 24, in that sequence, and ledge 11 is thereby captured by tabs 15 and 16, in that sequence.

It is preferred that surface 29 not comprise U-shaped slots as a portion of section 1 must be inserted into section 2 so connect the two sections. That portion of section 1 inserted for minimum connection is unavailable for use of the device, so providing U-shaped slots on that surface would not be useful. It is known that the number of metal surgical instruments that will be used in the invention device are relatively heavy. Therefore, a substantial portion of section 1 must be inserted into section 2 to prevent section 1 accidentally from slipping apart from section 2 in use. However, Figure 37 shows bump 57 that will pass with substantial user pressure on the ends of the assembly under the tabs but will resist being drawn back through them in operation for supporting surgical instruments.

A particular fault of the prior art organizers has been that ribs that could conceivably have been used to separate surgical instruments at their shanks have in operation failed for their intended purpose for being too short. While surgical instruments will remain separated with relatively short ribs if perfectly vertical, the fact of working with surgical instruments is that they fall from side to side against each other when one or more instruments are removed from a side by side group. Side by side and substantially vertically edgewise in the context of surgical instruments means that a lower finger ring rests on a support surface while an upper finger ring is held vertically above it while a tip

of the surgical instrument or a part of a shank are also supported on a support surface. The surgical instrument is prevented from falling on its side by other adjacent surgical instruments or a rib. In the other invention embodiments, a deep well or boxed end slot was described as necessary for vertically supporting the surgical instrument. In the present multi-level embodiment, it has been found that a combination of relatively short ribs for the upper and lower rows results in a stable operational slot for a single surgical instrument, if the user is given a choice of section 1 for smaller or shorted instruments and section 2 for larger or longer instruments. Upper and lower rows 12 and 18 can be provided with ribs as low as one fourth inch high from the bottom surfaces 14 and 20 respectively and with widths of about three eighths inches in width in combination with forward slanting U-shaped slots of about the same dimensions.

It is a surprising benefit of the present embodiment that such stable and separated support for surgical instruments can be put into a single device where section 1 for smaller instruments slides almost entirely into section 2 for larger instruments. A user is not prevented from using section 1 from larger instruments, but the stability of separation is reduced for the larger instruments. Large instruments are longer so that their lowest shank in a vertical edgewise position is raised substantially higher than the corresponding shank in a smaller instrument. Generally, a dividing measure of small and large instruments is about eight inches. Raising the height of a lowest shank of an instrument in a vertical edgewise position means that a shank rib in an upper row must be higher to keep from falling sideways. In the present embodiment, the upper row 7 of section 2 is adapted to easily abut such lowest shanks of surgical instruments ten or more inches long. In addition, the upper row 22 of section 1 is adapted to provide the most effective separation (preventing side to side falling over) for instruments in the range of four to eight inches long.

Figures 38 and 39 show that section 2 comprises a front wall 32 at a front side 9 and rear riser wall 32, the pair rising to upper row 7 with elevation 34. Figure 40 shows that section 1 has a front wall 30 and a rear riser wall 58, the pair rising to upper row 22. The U-shaped slots of upper row 7 are inclined frontward at about 5-10 degrees, minimized so that an underside cavity can remain sufficiently large to receive the

highest elevation of the tops of ribs 25 of upper row 22 of section 1. The U-shaped slots of upper row 22 of section 1 are inclined frontward at a steeper angle so that short instruments can have their lower finger ring rest in the slots of lower row 18 while the tip of the instrument can rest on the horizontal surface on which the assembly is supported. This it a critical requirement of a compact organizer where the upper row is located adjacent in a top view to the lower row. For a compact organizer, if the bottom surface of the U-shaped slot of the upper row is too high, the lowest shank resting on that surface will be a fulcrum and the instrument will become a lever rocking back and forth out of contact with the lower row ribs. The instrument will then fall sideways.

Figures 41 and 42 show sections 1 and 2 connected by sliding end 36 of section 1 into the end of cavity 43 (as in Figure 44) just far enough to keep them together in operation. Figure 41 shows that upper row 7 of section 2 has a substantially higher elevation than upper row 22 of section 1. Those figures show that tabs 15 and 28 secure ledges 11 and 10 respectively.

Figure 43 shows an end view of sections 1 and 2 as they would look either in Figures 41 and 42 or with section 1 slid almost completely into section 2. Figure 45 shows the interface 42 and 44 between the upper surfaces of section 1 and the underside of the cavity 43 (in Figure 44) of section 2. The top and bottom rows of section 1 are respectively adapted to lie beneath the top and bottom rows of section 2 in the fully nested position. Interface 42 is meant to be fairly tight so that the sliding connection is secure. Interface 43 is of greater distance so that the other portion of the upper surface of section 1 will slide easily under section 2 for storage.

In operation, section 1 is fully nested in section 2 and is shipped as a sterile or non-sterile product to a surgical center or hospital. When needed for surgical instrument organization, section 1 is withdrawn from section 2 in a direction 40 only sufficient for the number of instruments that will be used in the procedure. Space is saved by keeping the withdrawal of section 1 from section 2 to a minimum.

Figures 46 and 47 show respectively a small instrument on section 1 and a large instrument on section 2. Figure 46 shows that a critical feature, a retention bump or rib 48, may be added to help retain the lower finger ring 46 in the U-shaped slot. Figure 46

shows that a similar critical feature, a retention bump or rib 56, may be added to help retain the lower finger ring 53 in the U-shaped slot. Figure 46 shows a small instrument 45 comprising a pair of pivoted shanks 47 ending proximally in finger rings 46 and having a longitudinal axis of rotation 51 from the vertical edgewise position shown, i.e., the instrument can fall sideways if not supported. Figure 47 shows a large instrument 52 comprising a pair of pivoted shanks 54 ending proximally in finger rings 53 and having a longitudinal axis of rotation 55 from the vertical edgewise position shown, i.e., the instrument can fall sideways if not supported.

Figure 46 shows that lower finger ring 46 rests on bottom surface 20 and between ribs 19 to form an interface 59. Immediately adjacent and above the lower row is an upper row with bottom surface 26 and a pair of ribs 25 forming a support interface with the lower shank close to the lower finger ring 53. The tip of instrument 45 rests on a horizontal surface that supports section 1. The instrument's interface with the slot of the lower row, the slot of the upper row and the horizontal support surface form the means by which instrument 45 is maintained in a substantially vertical edgewise position, i.e., within about 30-45 degrees in either direction 51 without falling over or out of the organizer. A similar effect is made on instrument 52 with its interface 57, its lower shank interface in the upper row and with its tip resting on the horizontal support surface for section 2. A short downward extension 39 (in Figure 44) is made to make the supported surface of section 2 even with the ledges 17 and 27 of section 1 when section 1 is connected to section 2.

It is well illustrated that the upper rows of sections 1 and 2 comprise elevated ribs, respectively for ribs 21 and ribs 3, 6, and 8. The elevated ribs provide easy grouping of instruments placed on the organizer for sorting, i.e., the instruments laid on the upper row initially are divided in groups separated by the elevated ribs. This makes visual counting easy and prevents a total upset of the instruments if the assembled organizer is severely tilted. The instruments may rise from secure positions in their U-shaped slots, but the elevated ribs prevent the instruments from spilling out of the organizer altogether.

The objects of the invention will be achieved with other shaped slots than U-shaped slots, i.e., with V-shaped slots, etc. Such other shapes are intended when reference is made to U-shaped slots in this application.

Figure 48 is a rear and perspective view of an alternate embodiment of the assembly of Figure 42. Figure 48 shows that ribs 13 of section 2 rise substantially higher than the functionally equivalent ribs 19 of section 1. The height difference is to accommodate maintaining surgical instruments of substantially larger ring handle diameters in an edgewise vertical position, where the smaller ring handle diameters found in shorter surgical instruments are adapted to maintain that position with lower ribs 19 in section 1. Figure 48 also shows that a short rear walls 61 and 62 are added to improve retention of the surgical instruments.

Figures 49 through 57 shows a disposable and stackable instrument organizer. This organizer device 100a has substantially the same capabilities for instrument organizing and support as those of counters 100 shown in Figures 1 through 14 and described above. The stackable organizer of Figures 49 through 57 comprises multiple fenestrations and slots that reduce weight (and therefore cost) while keeping the strength and abilities of counter 100 of Figure 1. Device 100a of Figures 49 through 57 comprises four or more adjacent supporting means 101a that are analogous to counter sections 100 of Figure 1. Supporting means 101a each share at least two U-shaped support loops 102a and 107b with each adjacent supporting means 101a. Supporting means 101a comprise a lower support and upper support.

Each device 100a is adapted to support surgical instruments as described above. The surgical instruments have a single pivot connection for two long shanks at about a midpoint of those shanks and have two finger rings at proximal ends of two pivoted shanks. Device 100a has four or more adjacent supporting means 101a secured to a rectangular box base formed with base length walls 106a and base end walls 107h.

Each of the supporting means 101a extends laterally and perpendicular to the base length walls 106a and is adapted to support substantially edgewise a single surgical instrument of substantially any length from only one of the finger rings and lateral sides of the shanks so that distal ends of the shanks lie on a tabletop when the box base

rests thereon. As described above, each supporting means 101a further comprises a lower support and an upper support

A lower cavity contains the lower supports. The lower cavity is defined by an inside surface of one of the base length walls 106a, inside surfaces of the base end walls 107h, a cavity floor 107e, and an inside surface of a cavity forward wall 107g substantially adjacent to rearward edges of the upper supports and upper floor 104a. The lower supports each comprise two upside down and vertical U-shaped lower support loops 107b spaced apart, parallel and secured at legs in rearward and forward locations 107c and 107d respectively in the cavity floor 107 e to form a ring handle slot 107a adapted to receive and support the ring handle of a surgical instrument.

Lower loop slots 107f are defined in the lower cavity floor 107e vertically beneath each lower support loop 107b, each lower loop slot 107f having a width greater than a thickness of the lower support loops 107b.

An upper floor 104a extends from a top edge of the cavity forward wall 107g to the second base length wall 106a, where upper supports each comprise two upside down and vertical U-shaped lower support loops 102a spaced apart, parallel and secured at legs in rearward and forward locations 102c and 102d respectively in the upper floor 104a to form a shank slot 103a adapted to receive and support the lateral sides of the pivoted shanks of a surgical instrument. Upper loop slots 102e are defined in the upper floor 104a vertically beneath each upper support loop 102b. Each upper loop slot 102e has a width greater than a thickness of the upper support loops 102b.

Figure 54 shows that device 100a is being moved to be stacked on device 100b below it in direction 100c. Slots 107ff of device 100a can be seen as being aligned above loops 107b of device 100b. In a stacking position, slots 107ff of device 100a will each receive one of the top sections of loops 107b of device 100b. Similarly for the stacked position, upper loop slots of device 100a will each receive one of the top sections of upper support loops 102a of device 100b. Figures 55 and 56 show that devices 100a and 100b are compactly stacked as a result of providing loops and slots for a unitarily molded device 100a and 100b. Loop slots and support loops are each possible only because of the other's presence in the design.

Figures 56 and 57 show means for connecting the devices 100a and 100b end to end. Lug 300a slides into slot 300b to force the end walls 107h of adjacent devices 100a and 100b into very tight and rigid end to end connection. These connection means allow the user to easily increase the effective length of the instrument organizer so more surgical instruments can be supports as needed.

The above design options will sometimes present the skilled designer with considerable and wide ranges from which to choose appropriate apparatus and method modifications for the above examples. However, the objects of the present invention will still be obtained by that skilled designer applying such design options in an appropriate manner.